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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,863	06/24/2003	Reid W. von Borstel	1331-408	7194

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EXAMINER	
OWENS JR, HOWARD V	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,863	VON BORSTEL ET AL.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27 and 58-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27 and 58-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/7/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

Claims 27 and 58-72 are objected to for use of the term inflammatory antecedent to hepatitis. Hepatitis is defined as *"An inflammation of the liver characterized by diffuse or patchy necrosis affecting all acini (Merck Manual)"*, therefore, inflammatory hepatitis is redundant or construes that there is a non-inflammatory form of hepatitis and an inflammatory form

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 58-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of inflammation caused by hepatitis, does not reasonably provide enablement for the prevention of inflammatory hepatitis nor the use of inhibitors of uridine phosphorylase

broadly. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in In re Wands 8USPQ 2d 1400. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,
7) breath of the claims and the
8) level of skill in the art.

Quantity of experimentation necessary, Amount of guidance presented, Presence or absence of working examples

The instant claims are drawn to a method for treating a method for treating or preventing inflammatory hepatitis consisting essentially of administering to an animal a therapeutically effective amount of an inhibitor of uridine phosphorylase. The claim language suggests that hepatitis may be prevented in an animal via administration of an inhibitor of uridine phosphorylase. The specification teaches use of the compounds to treat systemic inflammation from a variety of causes, i.e. sepsis, hepatitis, etc.; but there is no suggestion that hepatitis may be prevented. Hepatitis has 3 distinct forms which vary in the form of treatment and transmission, thus any claims to preventing these forms should be adequately supported. The prior art, Decker, K. et al; "Galactosamine Induced Livery Injury"; Progress in Liver Diseases; (1972); Vol. 4. pp. 183-199, teaches that "hepatitis like" liver damage, meaning damage to the liver reminiscent of hepatitis, but not actual hepatitis infection, is preventable or treatable via uridine

administration, however, the prior art does not support the prevention of hepatitis nor the treatment of it broadly. Moreover, the compounds in the specification that are properly supported for the treatment of inflammation are limited to acyl derivatives of uridine. Applicant lists inhibitors of uridine phosphorylase (p.27), however the use of these inhibitors is limited to use in a composition with a nucleotide precursor, there is no guidance nor suggestion for the use of the inhibitors alone nor is there any evidence that administration of the inhibitor prevents hepatitis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 27 and 58-72 are rejected under 35 U.S.C. § 103 as being unpatentable over Von Borstel WO 890387 and Decker et al., "Galactosamine Induced Livery Injury"; Progress in Liver Diseases; (1972); Vol. 4. pp. 183-199; XP-008029633, in combination with Chu et al. (4,613,604).

Claim 27 and 58-72 are directed to a method for treating or preventing inflammatory hepatitis comprising administering a uridine phosphorylase

inhibitor wherein the inhibitor is chosen from known inhibitors or acylated uridine derivatives.

Von Borstel et al. teaches the treatment of hepatopathy (any liver disease) with acylated uridine or (21-29). Decker teaches that with hepatitis like liver injury, administration of uridine or an analog thereof (specifically 6-azauridine) prevents hepatitis like liver damage (p. 183 and 193). Neither Decker nor Von Borstel suggests inhibitors of uridine phosphorylase; however, Chu et al. teaches (col. 2, lines 30-50) that uridine phosphorylase inhibitors are potentiators of uridine derivatives; thus the teachings of Chu et al. that uridine phosphorylase inhibitors increase the amount of available uridine adequately bridges the nexus between the teachings of Von Borstel/Decker and the instant claims for the use of uridine phosphorylase inhibitors to increase the levels of free uridine serum or tissue levels.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use a uridine phosphorylase inhibitor to treat inflammation caused by hepatitis.

A person of ordinary skill in the art would have been motivated to use a uridine phosphorylase inhibitor because these inhibitors enable a systemic increase in the amount of available uridine, wherein uridine has been established in the prior art as a compound beneficial for the treatment/prevention of hepatitis like liver injury.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.